

**MINUTES OF THE MEETING  
OF THE  
BOARD OF PHARMACY**

**July 7, 2005**

**ROLL CALL**

Richard Zarek, R.P., Chair, called the meeting of the Board of Pharmacy to order at 12:05 p.m. in Lower Level Conference Room C of the State Office Building, located at 301 Centennial Mall South, Lincoln, Nebraska. Copies of the agenda were sent to Board members and other interested parties prior to the meeting. The following Board members answered the roll call:

Richard Zarek, R.P., Chairperson  
C. Curtis Barr, R.P. Vice-Chairperson  
Kevin Borchert, R.P., Secretary

Absent: Roger Kaczmarek, R.P.  
Linda Labenz

A quorum was present, and the meeting convened. Also present from the Department were: Becky Wisell, Section Administrator; Tony Kopf, R.P., Ronald Klein, R.P., and Mike Swanda, R.P., Pharmacy Inspectors; Cecilia Curtis-Beard, Credentialing Specialist; Joyce Davidson, Regulatory Analysis and Integration Division; Roger Brink, Department Legal Counsel; Ronald Hospodka, R.P., Creighton University School of Pharmacy and Health Professions; Charles Krobot, R.P., University of Nebraska College of Pharmacy; Lisa Anderson, Assistant Attorney General; Joni Cover, Executive Vice-President of the Nebraska Pharmacists Association (NPA); and Kelly Boryca, Pfizer.

**REVIEW OF AGENDA**

**Additions, Modifications, Reordering and Adoption of Agenda**

Wisell requested that a closed session be added at the end of the agenda so that Lisa Anderson could consult with the Board regarding a pending investigative case. Barr moved, seconded by Borchert, to approve the agenda, as amended, with the Chair having the authority to rearrange as needed. Voting aye: Barr, Borchert, Zarek. Voting nay: none. Absent: Kaczmarek, Labenz. Motion carried.

**Adoption of the Consent Agenda**

Barr moved, seconded by Borchert, to approve the consent agenda. Voting aye: Barr, Borchert, Zarek. Voting nay: none. Absent: Kaczmarek, Labenz. Motion carried.

**(3A) Pharmacist Applications with Misdemeanor/Felony Convictions (3) – Consent**

**(3B) Pharmacist Applications with Disciplinary Action (1) – Consent**

Labenz joined the meeting at 12:17 p.m. by telephone conference call.

**APPLICATION REVIEW**

**Pharmacist Applications with Misdemeanor/Felony Convictions (3) – Consent**

**Pharmacist Applications with Disciplinary Action (1) – Consent**

## **REVIEW AND APPROVAL OF PUBLIC HEARING COMMENTS**

### **172 NAC 128 Regulations Governing the Practice of Pharmacy**

The Board reviewed the summary of comments that were received at the public hearing on June 2, 2005, regarding the proposed amendments to these regulations. Following is a summary of the comments and the Board's responses to those comments.

Kevin Nicholson, R.Ph., J.D., Director, Pharmacy Regulatory Affairs, National Association of Chain Drug Stores.

Thanked the Department for recognizing that patients are not counseled in all situations – they are counseled when they accept an offer to be counseled. (128-015.02) The Board determined that no change was necessary.

Joni Cover, Executive Vice-President, Nebraska Pharmacists Association (NPA)

128-003.01 (6)(a)(11) Recommend that the “actions” listed in 11(a) and 11(b) mirror each other if possible. Is 11(c) repeating 11(a) and/or 11(b)? The Board approved these changes, adding “restricted” to 11(a); adding “denied” to 11(b); putting the actions of both (a) and (b) in alphabetical order; and keeping 11(c) as it is.

128-003.04 (1) Recommend that “jurisdiction” be added to line 1. (Be duly licensed/registered by examination in another state/jurisdiction in which, . . .). The Board approved this change.

128-003.07 The term “PharmD” should also be included in this list. The Board decided not to make this change because “PharmD” is a degree rather than a credential or a designation. The Board decided to delete 128-003.07 item 6 in total.

128-004.01 (4)(e) “Copies of arrest records;” should be (2), and the following requirements renumbered. The Board approved this change.

128-004.02B (5) & 128-004.03A (6) Recommend that “since the last renewal” be added to that sentence. Since the renewal is every two years, the department should have prior renewal information on file. The Board approved these changes.

128-006.01A1 (2) The correct title for NCCPE is Nebraska Council on Continuing ~~Pharmacy~~ Pharmaceutical Education. The Board approved this change.

128-006.03 Recommend that the second sentence be changed to read: “Licensees selected for audit are required to produce documentation . . .” or similar language. The Board approved this change.

128-016 Recommend that the Controlled Substances Act also be cited in this section. In addition, recommend that “causing to be shipped” also be added to this section in line 3. The Board decided not to cite the Controlled Substances Act in this section because the definition of prescription drug that is already cited is inclusive of controlled substances. The Board decided not to add “causing to be shipped” to this section because there is no statutory authority for this change.

128-016.01 Recommend that this section also include “jurisdiction and territory.” The Board approved this change, but it should be “jurisdiction or territory.”

The proposed regulations allow 150 to 180 days in which the department must act on granting licenses, renewing licenses, grievances, etc. The NPA feels that 150 to 180 days is rather lengthy, and suggests no more than 100 days for which the department must act. The Board decided not to make this change. This provision is based on the Administrative Procedures Act (APA). Although the Board could establish a timeframe that is less than the APA timeframe, the Board chose not to do so. In most cases, licensure decisions are made by the Department in much less than the maximum time allowed; however, it is helpful to have 150 to 180 days in situations that may require investigation or those that involve extenuating circumstances.

Fred Brinkley, Jr., P.Ph., MBA, V.P. Professional Affairs, Pharmacy Regulatory Group, Medco Health Solutions, Inc.

128-016.02C 1 and 128-016.03A the citations in reference to the Act are listed as 172 NAC 128. The citations in both sections SHOULD read 172 NAC 128-016. The Board approved these changes. Sections 128-016.02C item 1 and 128-016.03A item 1 will both have “-016” added following 172 NAC 128.

The Board also reviewed more recent financial information and expressed concern that the proposed fees in 172 NAC 128 for initial licensure and renewal licensure may have been reduced too far. The Board was concerned about reducing the cash balance too much that could result in a need to increase fees prior to the next license renewal in 2008. The Board consulted with Brink regarding whether an additional public hearing would be necessary if they chose to change the proposed fees for initial licensure and renewal licensure. Brink advised that because the notice of public hearing for these regulations referenced fee changes in a general sense and because the fee desired by the Board would still be a reduction in fees rather than an increase, an additional public hearing would not be necessary. Barr moved, seconded by Labenz, to change the fee for initial pharmacist licensure by examination, score transfer, and reciprocity from \$50 to \$75, and to change the fee for pharmacist license renewal from \$50 to \$75. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: none. Absent: Kaczmarek. Motion carried.

Barr moved, seconded by Borchert, to approve the 172 NAC 128 Regulations Governing the Practice of Pharmacy, as amended. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: none. Absent: Kaczmarek. Motion carried.

The Board requested that a copy of the proposed changes in the 172 NAC 128 regulations be sent to the Board members and also that copies be sent to the Board of Health for approval at their meeting on July 18, 2005.

### **175 NAC 8 Regulations Governing Licensure of Pharmacies**

The Board reviewed the summary of comments that were received at the public hearing on June 2, 2005, regarding the proposed amendments to these regulations. Following is a summary of the comments and the Board’s responses to those comments.

Kevin Nicholson, R.Ph., J.D., Director, Pharmacy Regulatory Affairs, National Association of Chain Drug Stores.

Thanked the Department for recognizing that patients are not counseled in all situations – they are counseled when they accept an offer to be counseled. (8-005.03A (7) and 8-006.04H1) The Board determined that no change was necessary.

175 NAC 8-006.04A Ask that the Department clarify the proper expiration date for drugs in medication cassettes that have been filled with drugs from different lot numbers and expiration dates. Under Rule 175 NAC 8-006.04A3, the proper expiration date would be the shorter of the manufacturer’s/distributor’s expiration date or one year from the date of transfer to the cassette. Under Rule 175 NAC 8-006.04A5, the proper expiration date would be a maximum of six months. Please provide clarification of this apparent inconsistency.

Charles Krobot, Pharm.D., Associate Dean for Academic Affairs, University of Nebraska College of Pharmacy

175 NAC 8-006.04A3 The expiration date for drugs transferred to cassettes is represented as “a maximum of one year from the date of transfer.” However, in section 006.04A5, the expiration date is represented as “a maximum of six months.” This appears to be a conflict. The original intent was for all expiration dates to be for one year.

Barr moved, seconded by Labenz, to delete section 8-006.04A5 in total and renumber the following two sections accordingly because the Board believes this section could create the potential for a misbranded drug to be placed on the shelf in a pharmacy. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: none. Absent: Kaczmarek. Motion carried.

Joni Cover, Executive Vice-President, Nebraska Pharmacists Association (NPA)

175 NAC 8-002 Recommend updating the definitions of compounding, signature, and adding the definitions of facsimile, electronic signature, and electronic transmission to mirror the statutory changes in Neb. Rev. Stat. §71-1,142 that were recently passed in LB 382. The Board decided to add the new statutory definitions of compounding and signature based on LB 382 because these are terms that are currently defined and used throughout 175 NAC 8. However, since the terms facsimile, electronic signature and electronic transmission are not currently used in the text of 175 NAC 8, there is no need to include these definitions in the regulations.

Hospodka asked about whether the verbal offer to counsel in 8-006.04H was stated clearly enough that it would be understood that counseling is required. Concern was expressed that this wording may allow for the verbal offer to counsel to occur, but the actual counseling may not take place even if the patient desired to have counseling. The Board determined that no change in the language would be necessary because 8-006.04H2 clearly sets out the only circumstances in which patient counseling does not have to occur.

Based on this discussion about the verbal offer to counsel, it was noted that in the 172 NAC 128 regulations in section 128-009 item 2, failure to conduct patient counseling is considered unprofessional conduct unless specifically exempt by law. Hospodka suggested that the proper statutory citation of Neb. Rev. Stat. §71-1,147.35 be included in this section rather than just referring to “by law” so that persons reading the regulation would know where the requirement for counseling is located in the law. Borchner moved, seconded by Barr, to modify 172 NAC 128-009 item 2 to reference Neb. Rev. Stat. §71-1,147.35 and to re-adopt 172 NAC 128 Regulations Governing the Practice of Pharmacy with this change. Voting aye: Barr, Borchner, Labenz, Zarek. Voting nay: none. Absent: Kaczmarek. Motion carried.

Hospodka also asked the Board whether 175 NAC 8-006.05C6 item 1 could be revised to include the requirements for destruction of oral controlled substances that were changed through the passage of LB 382 in the 2005 legislative session. Since the definitions of certain terms from LB 382 were updated in this chapter of regulations, he recommended that this recent statutory change also be incorporated into these regulations. Wisell and Davidson expressed concern about including this change because the regulation may involve more than just repeating the statutory language as was done for the definitions of compounding and signature. Such a change may require another public hearing. Borchner moved to modify 8-006.05C6 item 1 to include the destruction of oral controlled substances as referenced in LB382. The motion died for lack of a second.

Labenz moved, seconded by Barr, to approve 175 NAC 8 Regulations Governing Pharmacies, as amended. Voting aye: Barr, Borchner, Labenz, Zarek. Voting nay: none. Absent: Kaczmarek. Motion carried.

**CREDENTIALING REVIEW FOR THE REGISTRATION OF PHARMACY TECHNICIANS**

Zarek reported that the public hearing on the Board’s proposal for the registration of pharmacy technicians was held this morning. No opposition was presented at the hearing. Barr testified in support of the proposal on behalf of the Board. Cover testified in support of the proposal on behalf of the NPA. The next meeting of the Technical Review Committee for this proposal will be held August 4, 2005.

**DRAFT AMENDMENTS TO LB 318 – WHOLESALE DRUG DISTRIBUTION**

Boryca and Barr provided a report to the Board regarding a meeting of interested parties to LB 318 that was held June 29, 2005, at Creighton University. Boryca provided copies of statutory language of how other states have handled the exemption of manufacturers from the pedigree requirements for wholesale drug distribution. The intention of the legislation is to increase regulation of the wholesalers – not the manufacturers. However, under the proposed language of LB 318, manufacturers would still be required to be licensed as a wholesaler in this state, but they would need to be licensed by FDA first. Therefore, the manufacturers would be held to the requirements in the Code of Federal Regulations (CFR) §205.

The examples of state statutes also included language regarding when electronic pedigrees would be required. It is difficult to establish an effective date for the electronic pedigrees because it is uncertain when the technology will be available. Boryca reported that there will eventually be a revised draft of LB 318 that will be considered again by the Legislature in 2006.

### **INVESTIGATIONAL REPORTS — CLOSED SESSION**

Barr moved, seconded by Borchert, to close the session at 1:50 p.m. for investigational reports. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: none. Absent: Kaczmarek. Motion carried.

Barr moved, seconded by Borchert, to reopen the session at 2:25 p.m. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: none. Absent: Kaczmarek. Motion carried.

### **ADJOURNMENT**

Barr moved, seconded by Borchert, to adjourn the meeting at 2:25 p.m. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: none. Absent: Kaczmarek. Motion carried.

Respectfully submitted,

(Signature on file with the Department)

Kevin Borchert, R.P., Secretary  
Nebraska Board of Pharmacy